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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,471	10/06/2000	Lorenzo Williams	0459-0490P	8775

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EXAMINER

GAKH, YELENA G

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 02/13/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/680,471

Applicant(s)

WILLIAMS, LORENZO

Examiner

Yelena G. Gakh, Ph.D.

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-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-36 is/are rejected.
- 7) ☒ Claim(s) 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Norway on 10/06/99. It is noted, however, that applicant has not filed a certified copy of the 1999 4873 application as required by 35 U.S.C. 119(b).

Drawings

2. The photographs in Figures 5 through 10 are of extremely poor quality. The Applicant is advised either to withdraw these Figures from the Application, or resubmit the Figures of better quality.

Specification

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claim are directed.

The following title is suggested: "A method for synthesis, separation and screening of multiple compounds in the same bulk of a stationary phase".

Claim Objections

4. Claim 3 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim, or amend the claim to place the claim in proper dependent form, or rewrite the claim in independent form. Any chemical reaction, recited in claim 1, involves a reaction mixture including chemical reagents. The examiner is not aware of any reactions, which do not involve reaction mixtures including chemical reagents.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-36 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites, "a method for preparing and **screening one** or more compounds". According to the "Academic Press Dictionary of Science and Technology", "*screening test*" is determined as "a test to determine the presence of a given substance or organism in a **large number** of samples". It is not clear, how it is possible to screen just one compound. Also, claim 1 recites as step (b), "**separating** the compounds", which cannot be done with one compound (one compound can be purified or isolated by TLC).

Claims 4 and 5 are not clear. What do they mean? It seems that the Applicant tried to differentiate between introducing reagents into the bulk of a stationary phase as mixtures and as individual reagents, however this is not expressed clearly. Also, the reagents can be introduced either **on** a surface, or **into** the bulk.

Claims 9 and 10 are not quite clear. What does it mean, "the reaction mixture is localized to a well-defined area"? Does it mean, that it is **introduced** to a well-defined area? Or is it localized **in** a well-defined area? It is not clear, what is the difference between calms 9 and 10.

In claim 11, how can various syntheses be performed to yield just one compound? Also, the claim is not clear regarding the steps of the method. How are these parallel synthesis performed?

In claim 12, what does it mean "synthesis of more compounds"? More than what?

Claim 19 recites, that the bulk of the stationary phase can be dispersed between inert backings, which makes unclear how the reagents can be introduced into the bulk.

A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the

explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 21 recites the broad recitation "10 μ m to 5 mm", and the claim also recites "10 μ m to 2 μ m" and "100 μ m to 250 μ m", which are the narrower statements of the range/limitation.

In claim 22, what is "an plastics backing"? Is this "a plastic backing"?

Regarding claim 33, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. **Claims 1, 3-11, 15, 16, 19, 20-27, 31-33** are rejected under 35 U.S.C. 102(b) as being anticipated by Margotat et al. (J. Pharmacol.Methods, Abstract).

Margotat discloses "conversion of 1-14C-labeled arachidonic acid (AA) [506-32-1] to TXB2 (I) [54397-85-2] by human platelets" as studied "by using a new, simple technique. Organic solvent extraction was avoided by spotting aliquots of the reaction mixture directly on TLC plates. The plates were developed in CHCl₃-MeOH-HOAc-H₂O (90:10:4:1), and the spots were visualized with I vapor and counted. In this way it was possible to study the kinetic

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parameters of the formation of I". This method involves synthesis, separation and screening of the compound directly on the TLC plate of a standard size in the ranges recited in claim 21.

Claim Rejections - 35 USC § 103.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 12, 17, 28 and 34-36** are rejected under 35 U.S.C. 103(a) as being unpatentable over Margotat in view of Frank (Tetrahedron, IDS).

Margotat does not specifically disclose the synthesis, separation and screening of combinatorial libraries of compounds. Frank teaches spot-synthesis of combinatorial library of peptides, which is carried on cellulose paper sheet.

It would have been obvious for anyone of ordinary skill to modify Margotat's method in order to apply it to the combinatorial libraries, as disclosed by Frank regarding the synthesis step for peptides, because simultaneous obtaining a variety of potentially active compounds is one of the major goals of modern bio/chemistry, and Margotat demonstrated the simple method of synthesis, separation and assaying of one biologically important compound on the same TLC plate.

Although Margotat in view of Frank does not specifically disclose using aluminum oxide as the stationary phase or the solvent mixtures, recited in claim 28, as a liquid phase, it would

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have been obvious for anyone of ordinary skill to use any of those, because aluminum oxide is a standard stationary phase for TLC along with silica gel, and because choosing the solvent mixture for developing TLC plate is a routine procedure in analytical chemistry.

11. **Claims 13-14** are rejected under 35 U.S.C. 103(a) as being unpatentable over Margotat in view of Frank and Hudak (US 6,034,361).

Margotat in view of Frank does not teach microwave-assisted synthesis.

Hudak emphasizes in the Background of the Invention, that using microwave heating to promote the progress of one or more sample preparation steps or chemical synthesis steps is well known in the art (col.1, lines 14-16).

It would have been obvious for anyone of ordinary skill to add microwave heating for assisting chemical reactions in Margotat-Frank method, because it is a well known technique of improving the efficiency of syntheses, as pointed out by Hudak. It would have been obvious to place the bulk of the stationary phase with the reagents into a microwave cave to provide such heating.

12. **Claims 2, 18, and 29-30** are rejected under 35 U.S.C. 103(a) as being unpatentable over Margotat in view of Frank and Reed (US 5,332,665).

Margotat in view of Frank does not specifically teach using polyacrylamide and electrophoresis for separating compounds.

Reed teaches immunoblot analysis of binding specificity of monoclonal antibodies, using electrophoresis on 12% polyacrylamide gels as a separation step and autoradiography as a method for analysis.

It would have been obvious for anyone of ordinary skill to modify Margotat-Frank method using electrophoresis on polyacrylamide gel, as disclosed by Reed, because it is one of the major techniques of separation in biochemistry along with TLC.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. *Sodickson et al.* (US 4,059,405) disclose a method and an apparatus for analysis of constituent carried in fibrous medium (e.g. paper). *Edwards et al.* (US 4,666,863) disclose an

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discloses a device for chemical analysis, comprising two foldable segments, on the first of which the reaction takes place, and the second of which allows assaying of the compounds. *Gordon (US 4,956,302)* discloses a lateral flow chromatographic binding assay device with a sample application well located adjacent to the chromatographic medium and offset upstream from the reaction site. *Chen (US 4,965,193)* discloses detection of microbial beta-lactamase using a spot test on a filter paper, while heating the reaction mixture in the spot and exposing it to UV light. *Baldeschwierler et al. (US 5,847,105)* disclose methods for performing multiple sequential reactions on a matrix.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yelena G. Gakh, Ph.D. whose telephone number is (703) 306-5906. The examiner can normally be reached on 9:30 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-5408 for regular communications and (703) 305-3899 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

YG

February 8, 2002


Jill Warden
Supervisory Patent Examiner
Technology Center 1700